

**REMARKS**

Reconsideration and allowance are respectively requested in view of the foregoing amendments and the following remarks.

Claims 1-33 are pending in this application.

**Regarding the § 112 Rejection**

Claims 11-13, and 25-26 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Office Action indicates that the reference to “additive solutions” is inherently included in the claims, and does not constitute a positive recitation.

Applicant has amended claims 10-13 and 24-26 to make the language of the claims definite and particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, Applicant has amended claim 10 such that it recites “a side port adapted for an infusion of at least one additive”. Claims 11, 12 and 13 have been amended accordingly to refer back to the proper antecedent basis found in claim 10.

Claim 24 has been amended to recite “wherein the at least one additive is pumped...”, to provide antecedent basis for the element in claims 25 and 26.

Having amended the claims so that proper antecedent basis is provided, Applicant respectfully submits that the claims are definite and particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Applicant respectfully requests that the § 112 rejection be withdrawn.

Regarding the § 103 Rejections

Claims 1-4, 6, 14-16, 18-22, and 27-32 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by Bonomini (U.S. Patent No. 4,269,708).

First, Applicant respectfully disagrees with the Examiner that Bonomini discloses a wearable dialysis module with capillary fibers that act as dialyzers along with a replaceable filter cartridge 31 that has sorbents to act to absorb toxins from the dialysis liquid. Applicant respectfully points out that Bonomini does not teach, allude to or render obvious a replaceable filter cartridge that is wearable. In fact, the replaceable filter cartridge 31 of Bonomini is specifically shown as part of a separate non-wearable device that is part of Figure 2 that shows a portable, but non-wearable, part of the Bonomini hemodialysis and/or ultra filtration apparatus. Furthermore, Bonomini does not teach a plurality of sorbents that act to adsorb toxins from the dialysis liquid. On the contrary, Bonomini only teaches and renders obvious a single replaceable cartridge 31 that is charged with a single absorption material, namely activated carbon. (Col. 5, lines 32-43) Bonomini does not teach, allude to or render obvious the use of multiple filter cartridges, nor does it teach, allude to or render obvious using various different types of adsorbents in a Bonomini filter cartridge.

Applicant also respectfully submits that Bonomini teaches and requires that the operation of the Bonomini portable apparatus has two distinct phases, namely ultra filtration and dialysis. (Col. 6, lines 24-28) In the ultra filtration phase, blood is drawn [by] the pump 13, whereas a reduced pressure is established in the dialyzer, on the dialysis liquid side, by means of pump 17, connected by shunt line 27 and line 29, to the outlet of dialyzer 10, while the output side of pump 17 is connected, via lines 19 and 22, to collection bag 21. Bonomini goes on to teach specifically that valves 26 and 28 must be suitably controlled to provide the ultra filtration fluid circuit. (Col. 6, lines 29-38) Bonomini does not teach, allude to or render obvious

microprocessor controlled pumps in a wearable ultrafiltration or dialysis device , but instead only discusses electronic control of the valves for each specific ultra filtration phase. There is no suggestion in Bonomini to electronically control anything but a valve in a portable ultra filtration or dialysis device.

During the Bonomini dialysis phase, ultra filtration is not performed, but rather only dialysis is performed when “valve 20 is switched to connect the output side of pump 17, via lines 19 and 23, to the inlet of the dialyzer, while valves 26 and 28 are switched to exclude shunt line 27, the circuit of the dialysis liquid then comprising filter cartridge 31, tank 24 and temperature control device 33. The dialysis phase then takes place for a predetermined time at the end of which the portable unit is disconnected from the patient’s blood vessels and is ready for the next operation” (assumingly for the next patient). (Col. 6, lines 39-50) Applicant strongly and respectfully submits that Bonomini ultra filtration is performed in its own phase and dialysis is performed in a separate phase. Ultra filtration is clearly not performed at the same time as the dialysis phase in Bonomini. In fact, Bonomini points out that there is a specific advantage to performing the ultra filtration phase prior to performing the dialysis phase in col. 7. In particular, Bonomini states it should be noted that the apparatus of the present invention, due to the complete separation between the ultra filtration and the dialysis phases, permits only standard hemodialysis to be performed, but also ultra filtration alone and dialysis alone by merely suitably adjusting the circuit for the dialysis liquid. (Col. 7, lines 33-40) As such, Applicant respectfully points out that Bonomini does not teach, allude to or render obvious “a microprocessor adapted to control a rate that excess fluid is removed from the dialysate while said at least one dialyzer is utilizing the dialysate to remove impurities from the blood” because Bonomini cannot perform both dialysis and ultrafiltration at the same time.

With respect to independent claim 1, this claim has been amended to include “a microprocessor adapted to control a rate that excess fluid is removed from said dialysate while said at least one dialyzer is utilizing the dialysate to remove impurities from the blood”. As such, Applicant respectfully points out that Bonomini does not teach, allude to or render obvious claim 1 and respectfully requests that this § 103 rejection be withdrawn.

Claims 2, 3, and 4, 6, and 14-16 are either directly or indirectly dependent on claim 1 and are therefore not obviated for at least the same reasons as stated above with respect to claim 1. As such, Applicant respectfully requests that the § 103 rejection be withdrawn and submits that claims 2-4, 6 and 14-16 are ready for allowance.

Independent claim 18 has been amended to recite “a microprocessor adapted to control a rate that excess fluid is removed from dialysate while said at least one dialyzer is utilizing the dialysate to remove impurities from the blood.” Claim 18 has further been amended to recite that “a first sorbent device contains a first sorbent and a second sorbent device contains a second sorbent; said first sorbent and said second sorbent being different compounds.” Applicant respectfully submits, as stated above, that Bonomini does not teach, allude to or render obvious, a microprocessor adapted to control a rate that excess fluid is removed from the dialysate while the at least one dialyzer is utilizing the dialysate to remove impurities from the blood. Indeed, Bonomini specifically requires that there is complete separation between the ultra filtration and the dialysis phases. (Col. 7, line 32-35). Furthermore, Bonomini is limited to teaching a replaceable filter cartridge 31 having a single absorption material, namely activated carbon. (Bonomini, Col. 5, lines 32-43) Thus, the plurality of sorbent devices recited in claim 18 wherein a first sorbent device contains a first sorbent and a second sorbent device contains a second sorbent such that the first sorbent and second sorbent are different compounds is not taught, alluded to, or rendered obvious by Bonomini. Furthermore, the first and second sorbent

devices are not a mere duplication of the essential working parts of the device that amounts to an obvious duplication of the disclosed prior art because each of the first and second filter devices contain a different sorbent. (See MPEP 2144.04) Applicant respectfully submits that claim 18 is therefore not rendered obvious by the cited art and respectfully submits that claim 18 is ready for allowance.

Claims 19-22 and 27-32 are either directly or indirectly dependent upon claim 18 and are therefore not rendered obvious for at least the same reasons as stated above with respect to claim 18. Applicant respectfully requests that the § 103 rejection for these claims be withdrawn.

Claims 5, 17, 20 and 33 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by Bonomini in view of Henne (U.S. Patent No. 4,212,738).

Claims 5 and 17 are each directly dependent upon claim 1. Henne does not alleviate the inadequacies of Bonomini by providing any teachings about a microprocessor adapted to control a rate that excess fluid is removed from the dialysate. As such, Applicant respectfully submits that claims 5 and 7 are not obviated by Bonomini in view of Henne and respectfully requests that the § 103 rejection be withdrawn.

Claims 20 and 33 are each either directly or indirectly dependent upon claim 18. Again, Henne, like Bonomini, does not teach, allude to or render obvious a microprocessor adapted to control a rate that excess fluid is removed from dialysate while said at least one dialyzer is utilizing the dialysate to remove impurities from the blood. Furthermore, Henne, like Bonomini, also does not teach, allude to, or render obvious a first sorbent device that contains a first sorbent and a second sorbent device that contains a second sorbent, wherein the first and second sorbents are different compounds. As such, Applicant respectfully submits that Bonomini, in view of Henne, do not teach, allude to, or render obvious claims 20 and 33.

Claim 8 was rejected under 35 U.S.C. § 103(a) as being rendered obvious by Bonomini in view of Henne and further in view of Greenwood (U.S. Patent No. 4,897,189).

Greenwood, like Bonomini and Henne, does not teach, allude to, or render obvious a microprocessor adapted to control a rate that excess fluid is removed from said dialysate while said at least one dialyzer is utilizing the dialysate to remove impurities from the blood. Claim 8 being indirectly dependent upon claim 1 is therefore not rendered obvious for at least the same reasons as stated above with respect to claim 1. Applicant respectfully requests that the § 103 rejection be withdrawn.

Claim 23 was rejected under 35 U.S.C. § 103(a) as being rendered obvious by Bonomini, in view of Scott (U.S. Patent No. 3,388,803).

Like Bonomini, Scott does not teach, allude to or render obvious a microprocessor adapted to control a rate that excess fluid is removed from the dialysate while said at least one dialyzer is utilizing the dialysate to remove impurities from the blood. With respect to claim 23, this claim is indirectly dependent upon claim 18 and is therefore not rendered obvious by Bonomini in view of Scott. Applicant respectfully requests that this § 103 rejection be withdrawn.

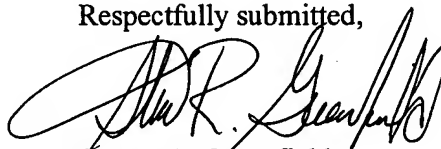
#### Miscellaneous Amendments

Applicant respectfully submits that all amendments made to the claims and not discussed with respect to the § 103 rejections above, were made to correct minor grammatical errors or to broaden the claims to cover allowable subject matter based on further review of the cited art. Applicant respectfully submits that all claims as presently submitted are ready for allowance.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Steven R. Greenfield", written over the typed name and registration number.

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